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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------|----------------------|
| 10/766,608 | 01/27/2004 | Robert F. Rioux | 03-226 US | 3377 |
| 23410 | 7590 | 05/08/2006 | EXAMINER ROY, ANURADHA | |
| Vista IP Law Group LLP 2040 MAIN STREET, 9TH FLOOR IRVINE, CA 92614 | | | ART UNIT | PAPER NUMBER 3736 |

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/766,608 | RIOUX ET AL. | |
| | Examiner | Art Unit | |
| | Anuradha Roy | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 December 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 3, 5, 6, 10, 12, 17, 18, & 24 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4,7-9,11,13-16,19-23, & 25-30 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/27/04</u> , see Other. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input checked="" type="checkbox"/> Other: <u>2/17/04 & 5/23/05</u> . |

DETAILED ACTION

Election to Restriction

Claims 3, 5, 6, 10, 12, 17, 18, & 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species. Applicant timely traversed the restriction (election) requirement on 14 December 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7, 9, 11, 13, & 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamm (US Patent No. 5,949,929).

Regarding claim 1, Hamm discloses a system for treating breast tissue, comprising:

- a cannula (111, 112, 119, & 134) having a proximal end, a distal end, and a first lumen (112) extending between the proximal and distal ends, the distal

end configured for insertion into a breast duct such that the first lumen is in fluid communication with the breast duct;

- and a tissue diagnostic device (40 & 46) disposed within the first lumen.

In regards to claim 2, Hamm discloses a system, wherein the tissue diagnostic device comprises a spectrometer (40 & 46).

Regarding claim 7, Hamm discloses a system, further comprising a media delivery device (114) coupled to the proximal end of the cannula.

Regarding claim 9, Hamm discloses a system, the cannula having a second lumen (119) extending between the distal and proximal ends, and capable of further comprising an imaging device (28 or 36 & Column 1, lines 39-67) secured to, or slidably disposed within, the second lumen.

Furthermore, regarding claim 11, Hamm discloses a system, wherein the imaging device is capable of comprising an endoscope (28).

With regard to claim 13, Hamm discloses a system, the cannula (Figure 4) having a second lumen (134) extending between the distal and proximal ends, and further comprising a device slidably disposed within the second lumen, the device selected from the group consisting of an electrode, an optical fiber (113), and an ultrasonic transducer.

Regarding claim 14, Hamm discloses a system, wherein the cannula (Figure 4) is adapted to deliver a substance to the breast duct, the substance selected from the

group consisting of a radiation seed, a toxic agent, a therapeutic agent, a necrosing agent, saline, and electrically conductive fluid (Column 5, lines 24-26).

Additional Claim Rejections - 35 USC § 102

Claims 15, 19-23, & 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Gatto (US Patent No. 6,840,909).

Regarding claim 15, Gatto discloses a system for treating breast tissue, comprising:

- a cannula (14 or 40) having a proximal end (29), a distal end (distal end of 12), and a lumen extending between the proximal and distal ends, the distal end configured for insertion into a breast duct such that the lumen is in fluid communication with the breast duct (Figure 1);
- an imaging device (12) for providing imaging functionality to the cannula;
- and an energy delivery device (49 & 50) secured to, or slidably disposed within the lumen of, the cannula.

With regard to claim 19, Gatto discloses a media delivery device (38 or 52) coupled to the proximal end of the cannula.

In regards to claim 20, Gatto discloses a system, wherein the cannula comprising a plurality of lumens (sections 12, 19, 20 including lumens 46 & 48) extending between the proximal and distal ends, and further comprising an aspirator (38 or 54) coupled to

the distal end of the cannula and configured to create a suction within one of the lumens.

With regards to claim 21, Gatto discloses a system, wherein the cannula (14 or 40) is adapted to deliver a substance into the breast duct, the substance selected from the group consisting of a radiation seed, a toxic agent, a therapeutic agent, a necrosing agent, saline, and electrically conductive fluid (Column 7, lines 59-62).

Regarding claim 22, Gatto discloses a system for treating breast tissue, comprising:

- a cannula (14 or 40) having a proximal end (29), a distal end (distal end of 12), and a lumen extending between the proximal and distal ends, the distal end configured for insertion into a breast duct such that the lumen is in fluid communication with the breast duct (Figure 1);
- an imaging device (12) for providing imaging functionality to the cannula;
- a media delivery device (38 or 52) coupled to the proximal end of the cannula;
- and an aspirator (38 or 54) coupled to the distal end of the cannula, the aspirator configured to create a suction within the lumen.

In regards to claim 23, Gatto discloses a system, wherein the imaging device (12) is secured to, or slidably disposed in the lumen of, the cannula.

Regarding claim 25, Gatto discloses a system, wherein the imaging device comprises an endoscope (12).

Regarding claim 26, Gatto further discloses a system, wherein the cannula (14 or 40) is adapted to deliver a substance into the breast duct, the substance selected from the group consisting of a radiation seed, a toxic agent, a therapeutic agent, a necrosing agent, saline, and electrically conductive fluid (Column 7, lines 59-62).

In regards to claim 27, Gatto discloses a system for treating breast tissue, comprising:

- a cannula (14 or 40) having a proximal end (29), a distal end (distal end of 12), and a first lumen (33) extending between the proximal and distal ends, the distal end configured for insertion into a breast duct such that the first lumen is in fluid communication with the breast duct (Figure 1);
- an energy delivery device (49 & 50) located at the distal end of the cannula;
- a media delivery device (38 or 52) coupled to the proximal end of the cannula;
- and an aspirator (38 or 54) coupled to the distal end of the cannula, the aspirator configured to create a suction within the first lumen.

With regard to claim 28, Gatto discloses a system, wherein the energy delivery device (49 & 50) is secured to the cannula, or slidably disposed within the first lumen.

In regards to claim 29, Gatto further discloses a system, wherein the cannula having a second lumen (48 & 49) extending between the proximal and distal ends, wherein the energy delivery device (52 or 82) is slidably disposed within the second lumen.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 & 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamm in view of Burbank et al. (US Patent No. 6,497,706).

Regarding claim 4, Hamm discloses a system for treating breast tissue, comprising all of the aforementioned elements. However, Hamm does not disclose an electrode slidably disposed with the first lumen of the cannula. However, Burbank et al. teaches the use of a slideable electrode (Column 2, lines 11-15 & Figure 2, 12 & 13). Since Hamm teaches of an optical fiber used to provide a conduit for conveying a light beam (i.e. energy), it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the optical fiber of Hamm with an electrode such as the one in Burbank et al. in order to provide a energy delivery system used for ablation of the breast tissue.

Regarding claim 8, as mentioned above Hamm discloses a system for treating breast tissue. However, Hamm does not directly disclose a system comprising an aspirator. Burbank et al., however, discloses a system using an aspirator (25). Since Hamm discloses a system utilized as to aid in-vivo optical biopsy (Column 1, lines 14-25), it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an aspirator such as that of Burbank et al. with Hamm in order to provide a clear path of visualization during the procedure.

Additional Claim Rejections - 35 USC § 103

Claims 16 & 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gatto in view of Burbank et al. (US Patent No. 6,497,706)

Regarding claims 16 & 30, Hamm discloses a system for treating breast tissue, comprising all of the aforementioned elements. However, Hamm does not disclose an energy delivery device comprising an electrode. Burbank et al., however, teaches the use of a slidable electrode (Column 2, lines 11-15 & Figure 2, 12 & 13). Since Hamm teaches of an optical fiber used to provide a conduit for conveying a light beam (i.e. energy delivery), it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the optical fiber of Hamm with an electrode, such as the one in Burbank et al. in order to provide a energy delivery system used for ablation of the breast tissue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-

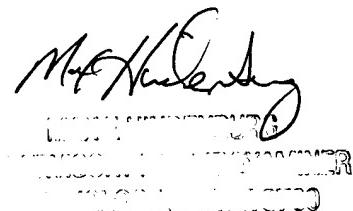
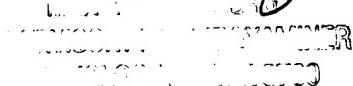
Art Unit: 3736

6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~

A handwritten signature in black ink, appearing to read "Max Hindenburg".
An official USPTO electronic signature stamp, featuring the agency's name and a unique identification number.